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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,401	06/25/2003	Stephen R. Hanson	18852-002002 / 5202B	3459

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,401	HANSON, STEPHEN R.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52,54-60 and 62-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,54-60 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-26-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment, arguments, and supplemental information disclosure statement, filed 7/20/2006, have been received. Claims 62 – 65 were added, and claims 53 and 61 are cancelled. Claims 50 – 52, 54 – 60, and 62 – 65 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 50 – 52 and 55 – 61 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 3, 5 – 7 and 13 – 15 of copending Application No. 11/127544 for reasons of record and those discussed below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' argument that "copending application do [*sic*] not recite nor suggest . . . devices adapted for long-term release of the agent.

This is not persuasive, because it amounts only to a general allegation of patentability. The previous office action already pointed out how the copending claims suggest the invention of instant claims. Absent any argument pointing out a specific flaw in this reasoning, the rejection must be maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 50 – 53 and 55 – 61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is **withdrawn** in view of amendment and Applicants' persuasive arguments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 52, 55 and 56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn**.

Claim 54 **remains** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' arguments have been fully considered, but are not persuasive.

Applicant points to numerous compound which are identified as being derivatives of anagrelide, and argues that since such compounds are known, the term is definite.

This is not persuasive, since regardless of how many so-called "derivatives" applicant may point out, there is no close-ended definition of the term "derivative" anywhere in the specification or the art, and as such, it is not possible for the artisan to understand what is included in this term, and thus, the artisan could not know the metes and bounds of the claimed invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites improper Markush language. Amending "among" to "the group consisting of" is suggested.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 50 – 53 and 55 – 61 under 35 U.S.C. 103(a) as being unpatentable over US 6,083,518 to Lindahl et al is **withdrawn**.

The rejection of claims 50 – 61 under 35 U.S.C. 103(a) as being unpatentable over US 4,432,980 to Flemming et al is **withdrawn**.

Claims 50 – 52, 56 – 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,083,518 to Lindahl in view of Physician's Desk Reference 1992, 790 – 792 (PDR).

Lindahl teaches compositions for the release of drugs, such as busulphan (claims 1, 10, abstract). Lindahl discloses that such compositions are useful for the ability to easily control the rate and duration of the active agent release (col. 2, col. 7 lines 62 – 67, lines 19 – 38).

Lindahl does not mention reducing platelet count in a subject, nor does Lindahl mention the duration or dosing of busulphan.

PDR discloses that busulphan is useful for reducing platelet count in a subject, and provides information on dosing and duration of treatment. PDR also discloses that busulphan is useful for treating leukemia. Leukemia, being a cancer of the blood and bone marrow, is a vascular disease or complication (the blood relating to the vasculature), as required. PDR also discloses when to stop treatment with busulphan in order to assure that desired levels of platelets result from treatment.

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to alter the dosing and duration of treatment with the controlled release device of Lindahl. The motivation to do so comes from PDR, which teaches the proper dosages and duration of treatment to effect the desired results. Since this information is known in the art, the artisan would enjoy a reasonable expectation of

success. Claim 62 is included since there is nothing of record to indicate that the device of Lindhal cannot be implanted. Note that instant recitation of "adapted for implantation" does not mean that the device must actually be implanted. Also, this terminology is not necessarily limiting. See MPEP 2111.04 [R-3].

Claims 52, 54 and 63 – 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindahl in view of Physician's Desk Reference 1992, 790 – 792 (PDR) and in further view of US 5,306,709 to Gewirtz.

The teachings of Lindahl and PDR are discussed above.

What is lacking is a teaching of anagrelide.

Gewirtz teaches that anagrelide is known to reduce platelet levels in patients (col. 2, lines 38 – 48).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to substitute anagrelide for busulphan in the invention of Lindahl. The motivation to do so flows from the teachings that these two agents have essentially the same function, that is, reducing platelet count. The artisan would thus expect to be able to achieve comparable results with either of these medications.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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